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REMARKS

Claim 53 is amended, as discussed below. Claims 40 and 41 are cancelled. Claims 31-39 and 42-54 are pending.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. Specification

The specification has been amended to update the "Cross-Reference To Related Applications," as requested by the Examiner.

II. Sequence Compliance

The specification has been amended at pages 35 and 37 to provide the appropriate SEQ ID NO's.

III. Claim rejections- 35 U.S.C. 101

Claims 53-54 are rejected under 35 U.S.C. 101 as directed to non-statutory subject matter on the basis that recombinant host cell can be still attached to a human body. The Examiner suggests adding the word "isolated."

Although Applicants disagree that these claims are drawn to non-statutory subject matter, the claims have been amended as suggested by the Examiner to expedite prosecution.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 101. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 31-54 under 35 U.S.C. 112

Claims 31-54 are rejected under 35 U.S.C. 112, as requiring a microbial deposit (E. coli DSM 13049).

Submitted herewith is a Statement under 37 C.F.R. 1.808, complying with the deposit requirement.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

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V. The Rejection of Claims 31-40 and 43-54 under 35 U.S.C. 112

Claims 31-40 and 43-54 are rejected under 35 U.S.C. 112 as being non-enabled. The Examiner states that while being enabling for a polynucleotide with SEQ ID NO:1 or a polynucleotide that hybridizes to SEQ ID NO:1 under high stringency conditions, that the claims are not enabled for any polynucleotide which encodes a polypeptide having either 80% identity to SEQ ID NO:2 or a polynucleotide that hybridizes to SEQ ID NO:1 under medium stringency conditions, or any polynucleotide having a nucleotide sequence that is 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to SEQ ID NO:1. This rejection is respectfully traversed.

Applicants appreciate the indication as to which subject matter is enabled, however, Applicants respectfully submit that the claims are enabled for polynucleotides which encode a polypeptide having glucanotransferase activity which is at least 80% identical to amino acids 1 to 501 of SEQ ID NO:2, polynucleotides that are 80%, 85%, 90%, 95%, 96%, 97%, 98% or 99% identical to nucleotides 1 to 1503 of SEQ ID NO:1, and polynucleotides that are at least 80% identical to the DNA sequence cloned into the plasmid present on *E. coli* DSM 13049.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46

(C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

The reasoning provided in the Office Action is that the specification does not provide sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides with an enormous number of modifications to SEQ ID NO:1. Applicants respectfully submit that this reasoning is not sufficient to render the claims non-enabled.

The claimed nucleic acid sequences are structurally similar because they encode a polypeptide having an amino acid sequence that have a high degree of identity to SEQ ID NO. 2 or they are polynucleotides that have a high degree of identity to SEQ ID NO. 1. The claims encompass polynucleotides encoding natural variants of SEQ ID NO:2 as well as those which can be made using routine molecular biological techniques. In this regard, enzyme isolation techniques and recombinant and mutagenesis techniques are well known in the art and it is routine in the art to screen for multiple substitutions or multiple modifications. The claims also encompass polynucleotides encoding conservative substitutions into SEQ ID NO:2, which are well known in the art. It is routine in the art to make conservative amino acid substitutions (on the DNA level) which can reasonably be expected to produce polypeptides that preserve the structure and function of the parent.

An artisan would have a reasonable expectation of being able to practice the claimed invention commensurate in scope with the claims as an artisan is routinely able to obtain, using the reference sequence as a starting point, highly homologous sequences. Indeed, the level of skill in the relevant art is very high. Thus, once apprised of Applicants' invention, it is simply routine to practice the invention, using, for example, well-known molecular biological techniques used for obtaining highly homologous nucleic acids and polypeptides. Indeed, one skilled in the art would have a very high degree of predictability of being able to make such sequences. That is, once provided with this new sequence, Applicants have enabled the skilled artisan to practice the invention by producing highly homologous polynucleotides.

The enablement rejection is also clearly inconsistent with the USPTO's prior determination in regard to U.S. Patent No. 6,617,143. Clearly, if an artisan is enabled to obtain the polypeptides having at least 80% identity to amino acids 1 to 501 of SEQ ID NO:2, they are also enabled to obtain the nucleic acids encoding same given the guidance provided in the specification.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 31, 40 and 51-54 under 35 U.S.C. 102

Claims 31, 40 and 51-54 are rejected under 35 U.S.C. 102 as being unpatentable over GenBank Accession NO. AAW83330. The Examiner states that the prior art discloses an amino acid sequence which is 62.5% identical to SEQ ID NO:2 and has glucanotransferase activity. The Examiner takes the position that the polynucleotide encoding same is capable of hybridizing to SEQ ID NO:1 under medium stringency conditions.

Applicants have canceled all of the claims based on hybridization, including both medium stringency and high stringency conditions. The Examiner has raised a possibility of hybridization under medium stringency conditions. Applicants have also not yet ruled out the possibility of hybridization under high stringency conditions. Applicants may further investigate both of these conditions in regard to the cited reference and hypothetical DNA sequence and revisit this subject matter in a continuation application.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 102. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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Jason J. Garbell, Reg. No. 44,116
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212)840-0097